PATENT
Attorney Docket No.: 50623.71

REMARKS

Please reconsider the application in view of the amendments indicated above and the remarks set out below.

- Claims 2, 4-18, 20-22, 29, and 30 are pending.
- Claims 2, 4-18, 20-22, 29, and 30 are rejected.
- Claims 23-28 are cancelled as non-elected.

Paragraph 8

Ex Parte Parks, 30 USPQ2d 1234 (Pd. Pat. App. & Inter. 1993) lays out the Patent Appeal Board's current announcements regarding new matter rejections as they relate to chemical cases and negative limitations.

> The initial burden of establishing a prima facie basis to deny patentability to a claimed invention on any ground is always upon the examiner.[1] In rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter.[2] Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention.[3] Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed.[4]
>
> The examiner contends that the rejected claims lack adequate descriptive support because there is "no literal basis for the" claim limitation "in the absence of a catalyst." Clearly, the observation of a lack of literal support does not, in and of itself, establish a prima facie

[1] In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).
[2] Wang Laboratories, Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).
[3] In re Herschler, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); In re Edwards, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978); In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).
[4] In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112.[5]

In the previous Office Action response, applicants discussed dialdehyde cross-linking and its overall unsuitability for applicants' hemocompatible coatings to illustrate that the balance of facts on the record show that the originally-filed disclosure would have conveyed to one having ordinary skill in the art that applicants had possession of the concept of what is claimed. Clearly, if applicants are both silent about dialdehyde cross-linking and the overall disclosure teaches species that are incapable of cross-linking through a dialdehyde group, then a fair reading of the disclosure is that applicants did not intend to teach any dialdehyde cross-linking with its hemocompatible substance.

Contrary to the Examiner's assertion that "the exemplary teachings of some coatings that happen to contain no dialdehyde cross-linking do not provide basis for claiming all possible coatings with no such cross-linking", the law says otherwise. The law is clear: adequate description under the first paragraph of 35 USC § 112 does not require literal support for the claimed invention; the lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate descriptive support.[6] Applicants teaching of some coatings that cannot undergo dialdehyde cross-linking teaches one of ordinary skill in the art that applicants had possession of coatings not containing dialdehyde cross-linking especially in view of the esoteric nature of dialdehyde cross-linking. To paraphrase Ex Parte Parks, "throughout the discussion which would seem to cry out for [dialdehyde cross-linking] if [it] were used, no mention is made of [dialdehyde cross-linking].[7] Since applicants had possession of the invention, applicants are entitled to claim the invention, at least according to the Board of Patent Appeals.

A reading of Ex Parte Parks shows a situation in which the word catalyst was never mentioned; yet, it was not new matter to add a negative limitation excluding a

[5] In re Herschler, supra; In re Edwards, supra; In re Wertheim, supra.
[6] In re Hersheler, supra.
[7] Ex Parte Parks, 30 USPQ2d at 1236.

catalyst from the claimed method. In the instant application, dialdehyde cross-linking is never mentioned and applicants seek to add a negative limitation excluding dialdehyde cross-linking from the claims.

Dialdehyde cross-linking requires that the hemocompatible coating have an accessible primary amine. Also, it requires that the hemocompatible substance retain its function after reaction with the dialdehyde cross-linking agent. These two characteristics will not hold true for most of the members of this hemocompatible coating genus. Specifically, it is impossible for the hydrophobic quaternary ammonium ions recited in Claim 9 to undergo dialdehyde cross-linking reaction because they do not have a primary amine.

The Examiner says that it appears that applicants' heparin compounds with quaternary ammonium ions contain primary amines. Applicants have attached dictionary definitions of quaternary ammonium compounds and amines to correct the Examiner's misapprehension. These definitions come from the IUPAC's Compendium of Chemical Technology and can be found at the IUPAC's web site. To put it succinctly, primary amines have only one N-attached R group, while quaternary ammonium compounds have four N-attached R groups. Applicants' quaternary ammonium ion does not contain a primary amine and heparin does not contain a primary amine. Therefore, applicants' heparin compounds with quaternary ammonium ions do not contain primary amines.

Paragraph 7

Applicants have amended Claim 29 in view of the Examiner's comments in paragraph 7.

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Paragraph 8

The Office Action rejects claims 29, 30, 5-11, 18, and 21-22 under 35 USC § 102(b) as being anticipated by Hsu, US patent number 4,871,357 (357).

The solubility of a salt depends upon the solubility of each ion in the solvent. Silver nitrate is insoluble in water even though nitrate ions are very soluble in water. This is because the overall thermodynamics of the dissolution process has the lowest energy when the silver nitrate is solid. So, if one tried to dissolve silver nitrate in hexane, the addition of water would not improve the solubility of the silver nitrate even though nitrate is very soluble in water.

To increase the solubility of a salt in a solvent the thermodynamic gains brought about by the preferred interactions must outweigh the thermodynamic losses brought about by the dis-preferred interactions. In the current discussion, the thermodynamic gains from the interaction of heparin with ethanol must lower the overall free energy of mixing more than the interaction of the stearyl alkonium interaction with the ethanol. There is no evidence of record that this is so. In fact, Hsu teaches that its benzyl alkonium ion heparin is highly hydrophobic and had limited solubility in polar solvents. The current office action continues to argue that Hsu inherently enhances the solubility of Hsu's compound. Examiner argument is in sufficient.

Inherency requires that the EVIDENCE make clear that the missing descriptive matter is NECESSARILY present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.[8] Applicants once again ask for EVIDENCE that clearly shown the missing descriptive matter is NECESSARILY present. Here, the missing descriptive matter is that the addition of ethanol to the solution of Hsu's alkonium salt will NECESSARILY result in the enhanced solubility of Hsu's salt in the solution.

The 357 patent disclosure shows that its heparin complex has "vastly superior hydrophobicity" compared to previous heparin complexes. (Column 4, line 13).

Furthermore, the goal of the 357 patent is to make the hemocompatible coating complex more like the substrate surface to improve its affinity for the surface. (Column 7, lines 31-34). Therefore, 357 as a whole teaches matching the hydrophobicity of the coating to the substrate. Since the 357 patent does not teach a second solvent that enhances the solubility of the hemocompatible coating substance in a mixture of a first solvent and a second solvent, it does not anticipate these claims.

Please remove this rejection.

Since independent claims 29 and 30 are not anticipated by the 357 patent, the remaining paragraph-8 discussion regarding claims that depend from Claims 29 and 30 is moot. Therefore, Applicants take no position as to whether the patent teaches the limitations described in the Office Action. Applicants will explain why the patent lacks these limitations, should that become necessary.

Paragraph 9

Claims 29, 5-7, and 18 are rejected under 35 USC § 102(b) as being anticipated by Drumheller, US patent number 5,914,182 (182).

The 182 patent teaches sequential deposition of a first solvent followed by deposition of a second solvent. It does not teach creating a mixture of a first and second solvent and dissolving a hemocompatible substance in that mixture as required by Claim 29, **as amended**. Therefore, the patent does not anticipate these claims.

Please remove this rejection.

Paragraph 10

Claims 2, 4, 12-15, and 20 are rejected under 35 USC § 103(a) as being unpatentable over the 357 patent, discussed above.

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[8] MPEP §2131.01.

The 357 patent does not teach a second solvent that enhances the solubility of the hemocompatible coating substance in a mixture of a first solvent and a second solvent, as is found in Claims 29 and 30, and therefore, in all claims that depend from Claims 29 and 30. The Office Action's obviousness-based rejection contained in paragraph 10 does not address this difference. Until an Office Action does so, prima facie obviousness has not been made out, and Applicants have no duty to address the rejection.

Please remove this rejection.

Since the 357 patent fails to teach the limitations described above, the remaining discussion in paragraph 10 regarding claims that are dependent from Claims 29 and 30 is moot. Therefore, Applicants take no position as to whether the patent teaches the limitations described in the Office Action. Applicants will explain why the patent lacks these limitations, should that become necessary.

Paragraph 11

The Office Action rejects claims 30 and 22 under 35 USC § 103(a) as unpatentable over Eriksson, US patent number 4,118,485 (485), in view of van Tassel, US patent number 6,241,710 (710).

Claim 30 recites a list of solvent classes as originally recited in claim 7. Eriksson combined with VanTassel does not teach this list or members of this list, as the list was amended.

The list was amended to remove fluoropolymer-wetting cyclohexane. Applicants' initial presentation of a solvent list with both fluoropolymer-wetting alkane and fluoropolymer-wetting cycloalkanes teaches one of ordinary skill in the art that Applicants have defined these different from each other. Therefore, fluoropolymer-wetting alkane is not properly construed to encompass fluoropolymer-wetting cycloalkanes, in view of the application and prior prosecution.

Therefore, the prior art relied on for this rejection does not contain each and every element of claim 30. Nor does it contain an explanation of why the missing elements

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would be obvious. Therefore, this obviousness rejection is moot with regard to claim 78 and its dependent claims, because of the newly added limitation.

Please remove this rejection.

If I can help you further or do anything to expedite the application's issuance, please contact me.

Respectfully submitted,

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amines

Compounds formally derived from ammonia by replacing one, two or three hydrogen atoms by hydrocarbyl groups, and having the general structures RNH2 (primary amines), R2NH (secondary amines), R3N (tertiary amines). 1995, *67*, 1316

quaternary ammonium compounds

Derivatives of ammonium compounds, NH4 + Y – , in which all four of the hydrogens bonded to nitrogen have been replaced with *hydrocarbyl* groups. Compounds having a carbon–nitrogen double bond (i.e. R2C=N + R2Y –) are more accurately called *iminium compounds*. e.g. [(CH3)4N] + OH – , tetramethylammonium hydroxide.

See *onium compounds.*

1995, *67*, 1361